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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/088,821	03/22/2002	Mitoshi Konno	Q69163	5233

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EXAMINER

SMALL, ANDREA D SOUZA

ART UNIT	PAPER NUMBER
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1626

DATE MAILED: 08/08/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

<p align="center">Office Action Summary</p>	<p>Application No.</p> <p align="center">10/088,821</p>	<p>Applicant(s)</p> <p align="center">KONNO ET AL.</p>	
	<p>Examiner</p> <p align="center">Andrea D Small</p>	<p>Art Unit</p> <p align="center">1626</p>	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above claim(s) See Continuation Sheet is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☒ Claim(s) 1-13 is/are objected to.
- 8) ☒ Claim(s) 1-13 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413) Paper No(s). <u>7/03</u> . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>03/02</u> . | 6) <input type="checkbox"/> Other: _____ |

Continuation of Disposition of Claims: Claims withdrawn from consideration are parts of 4-7, 9, 11 and 12 and claims 1-3, 8, 10 and 13.

DETAILED ACTION

I. Preliminary Matters:

- (a) Claims 1-13 are pending.
- (b) Applicants claim that this application is a 371 of PCT JP00/06506 09/22/2000 is acknowledged.
- (c) The information disclosure statement filed has been received and a signed and initialed 1449 is attached.

II. Restriction/Election:

- 1. Restriction to one of the following inventions is required under 35 U.S.C. 371:
- 2. The main categories of invention are as follows:
 - I. Claims 4-13, drawn to products of compound *of* claim 4.
 - II. Claims 1-3, drawn to IL-6 production inhibitors *comprising* the compound of claim 1.
- 3. The inventions listed as Groups I-II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

PCT Rule 13.1 states that the international application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept (requirement of unity of invention).

PCT Rule 13.2 state that unity of invention referred to in Rule 13.1 shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features.

Annex. B, Part 1(b), provides that "special technical features" mean those technical features, which, as a whole, define a contribution over the prior art.

Annex B, Part I(e), provides combinations of different categories of claims and states:

"The method for determining unity of invention under Rule 13 shall be construed as permitting, in particular, the inclusion of any one of the following combinations of claims of different categories in the same international application:

Art Unit: 1626

(I) in addition to an independent claim for a given product, an independent claim for a process specially adapted for the manufacture of the said product, and an independent claim for a use of the said product, or

(II) in addition to an independent claim for a given process, an independent claim for an apparatus or means specifically designed for carrying out the said process, or

(III) in addition to an independent claim for a given product, an independent claim for a process specially adapted for the manufacture of the said product, and an independent claim for an apparatus or means specifically designed for carrying out the said process...”

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 C.F.R. 1.499, applicant is required, in response to this action, to elect a single invention to which the claims must be restricted.

The inventions do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding technical features that defines a contribution over the prior art. The features that can be taken as a whole in common with both groups and within each group is $-\text{CH}(\text{OH})-(\text{CH}_2)_4\text{C}(\text{O})\text{NO}-$, these features do not provide a contribution over the art and hence do not qualify as a special technical feature over the art since these features was known in the art prior to the filing of the instant application, See Kato, et al. Each of the inventions in this applications represent a discrete compound which one skilled in the art which beside sharing no structural element, cannot be said to belong to a recognized class of chemical compounds. Accordingly, the unity of invention is considered to be lacking and restriction of the invention in accordance with the rules of unity of invention is considered to be proper.

Art Unit: 1626

4. The above grouped inventions themselves are inclusive of patentably distinct subject matter, which must be further restricted because patentably distinct species may be included together in a generic claim where the number of species is *reasonable* and where there is *no* serious burden on the examiner to examine all the grouped distinct species in one application. Accordingly, along with the election of one of the above groups, the following action is also taken.

5. It is to be noted that the following action is a restriction requirement placed on the instant claims; they are NOT being rejected as being an improper Markush claim. The entire contents of the claims will eventually be examined, either as elected subject matter in the instant application or as elected subject matter in divisional applications.

Claim 1 is generic to a plurality of disclosed patentably distinct species comprising, for example, the compounds of (1) Example 8, page 16, Example 10, page 16, etc., and (2) a method of treating a disease associated with IL-6 inhibition using the compounds as in Example 8, 10, etc. Each species differs one from the other in structure and element and have each acquired separate status in the art. For example, the morpholine ring at the R1 position of compound of formula I, may be classified in class 544, subclass 122+; the piperidinyl moiety at the R1 position of compound of formula I, is classified in class 546, subclass 152, etc. Examining these pluralities of distinct species in the same application would result in a serious burden during examination.

The search required, both electronic and manual database, for each of the patentably distinct species is separate and involves separate search considerations and search strategies. These searches are not co-extensive and the evaluation of the search

Art Unit: 1626

results are divergent, so much so that searching for a reference that would anticipate a reasonably grouped invention identified supra would not even render the non-elected invention obvious. Therefore, a serious burden would be placed on the office if restriction between these groupings were not required.

6. A precise listing of all the possible sub-groups of inventions that would fall under any of the above main invention groups cannot be made due to the sheer volume of species encompassed by the instant claims. Consequently, Applicant is required to elect a single disclosed species or single preferred embodiment of their invention, even though this requirement is traversed. Additionally, whatever specific compound is ultimately elected, applicants are required to list all claims readable thereon.

7. Upon the election of a single disclosed species (e.g. Example, page number and structural depiction) or a preferred embodiment of the invention, a generic concept, inclusive of the elected species, will be identified by the Examiner for examination. This generic concept will establish the elected group to be examined and the remaining subject matter not within the confines of the generic concept will be withdrawn as non-elected subject matter. This subject matter may then be pursued in divisional applications as is Applicants right under 37 CFR 1.142(b).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement is traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i)

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

8. In a telephone conversation with Mr. John Callahan on July 24, 2003, a provisional election was made with traverse to prosecute the invention of group II, claim 4-13, specifically the species of compound 96 in claim 11.

9. The generic concept:

Compounds of claim 4 wherein:

R1 is an (o) alkyl 1-8 substituted by Cyc1, wherein Cyc1 is selected from morpholine, piperidine and piperazine or ((v) C2-8 alkenyl substituted by Cyc1, wherein Cyc1 is selected from morpholine, piperidine and piperazine or (w) C2-8 alkynyl substituted by Cyc1, wherein Cyc1 is selected from morpholine, piperidine or piperazine;

m is 1;

A is a benzene ring;

B is a benzene ring;

E is as claimed in claim 4;

R8 is as claimed in claim 4;

n is as claimed in claim 4; and

R9 is as claimed in claim 4.

10. Claims readable on the elected group identified supra are 4-7, 9, 11 and 12. The remainder of claim 4-7, 9, 11 and 12 that does not read on the elected group as identified supra and claims 1-3, 8, 10 and 13 are withdrawn from consideration as being drawn to non-elected inventions. 37 CFR 1.142(b).

III. Objections:

(a) Claims 5 and 6 objected to because of the following informalities: Claims 5 and 6 recite the definitions of the R substituents in parenthesis, this does not comply with the formality requirements of a claim wherein parenthesis may be used when referencing characters in the detailed description in the specification or drawings, but these reference characters would then have no bearing on the scope of the claim. The recitation of R groups does have bearing on the scope of the claim, hence it is suggested that Applicants amend claims to delete the open and close parenthetical.

(b) Claims 4-7, 9, 11 and 12 are objected to for containing non-elected subject matter and if drawn solely to the elected group identified supra and overcoming any objections also cited supra would appear allowable.

(c) Claims 1-3, 8, 10 and 13 are objected to as being drawn to non-elected invention. 37 CFR 1.142(b).

IV. Closest Prior Art:

Art Unit: 1626

Applicants claims relate to hydroxamic acid compounds according to claim 4. The closest prior art, EP 737671, teaches structurally related compounds to those instantly claimed. The prior art, however, does not teach or fairly suggest the substitution of a alkyl, alkenyl, alkynyl substituted heterocyclic moiety such as morpholine, piperidine or piperazine at the A ring as instantly claimed.

V. Contact Information:

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Andrea D. Small whose telephone number is (703) 305-0811.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-1235.

A facsimile center has been established. The hours of operation are Monday through Friday, 8:30-6:30 PM. The number for accessing the facsimile machine is (703) 746-4984.



Andrea D. Small, Esq.
Patent Examiner
Art Unit 1626, Group 1620
Technology Center 1600

July 31, 2003